IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KANEKA CORPORATION, *Plaintiff*, v. DESIGNS FOR HEALTH, INC., and AMERICAN RIVER NUTRITION LLC. *Defendants*.	§ § § § § § § § § § § § §	Civil Action No. 21-209-WCB

FINDINGS OF FACT AND CONCLUSIONS OF LAW

This is an action for patent infringement under 35 U.S.C. § 271. Plaintiff Kaneka Corporation ("Kaneka") brought this action alleging direct and induced infringement of two of its patents, U.S. Patent No. 7,145,044 ("the '044 patent") and No. 7,829,080 ("the '080 patent"), by Defendants Design for Health, Inc., ("DFH") and American River Nutrition, LLC, ("ARN"). *See* Dkt. No. 75 (Second Amended Complaint). DFH and ARN asserted counterclaims seeking a declaration of non-infringement and invalidity of the '044 and '080 patents. *See* Dkt. No. 79.

The court granted the defendants' motion for summary judgment "to the extent that Kaneka will not be entitled to injunctive relief for infringement of the expired '044 patent," but denied it in all other respects. Dkt. No. 141 at 37. Kaneka then dropped its claims of infringement based on the '044 patent, and the case proceeded to a bench trial on claims 5 and 15 of the '080 patent. *See* Dkt. Nos. 143, 192. Kaneka alleges that DFH directly infringed those claims and that ARN induced DFH's infringement. *See* Dkt. No. 75.

The court bifurcated the trial on liability and damages, *see* Dkt. No. 203, and held a four-day bench trial on liability in late May and early June of 2024, *see* Dkt. No. 235–38. After the

bench trial, the parties filed proposed findings of fact and conclusions of law, and subsequently filed briefs in response.[1] Dkt. Nos. 231, 232, 240, 244.

BACKGROUND

Kaneka is a Japanese firm that manufactures and sells dietary supplement ingredients among other products. *See* TD1 at 7:20–8:10. The company manufactures and sells compositions containing the chemical compound ubiquinol as part of its dietary supplement ingredient business. *See id.* at 8:4–5; *id*. at 8:21–24. Ubiquinol is a form of Coenzyme Q_{10} ("CoQ_{10}"), which can exist in two states: an oxidized state and a reduced state. Oxidized CoQ_{10} is known as "ubiquinone," and reduced CoQ_{10} is known as "ubiquinol." *Id*. at 13:14–14:1.

Kaneka is the owner of the '080 patent, titled "Stabilization Method of Reduced Coenzyme Q_{10}." PTX 1. The specification of the '080 patent teaches that "reduced coenzyme Q_{10} is easily oxidized by molecular oxygen into oxidized coenzyme Q_{10} and therefore stabilization of reduced coenzyme Q_{10} is an important issue when it is processed into" various products, including

[1] At the close of the plaintiff's case at trial, the defendants filed three separate motions for judgment as a matter of law under Federal Rule of Civil Procedure 50(a). *See* Dkt No. 210 (motion for judgment as a matter of law of no direct infringement); Dkt. No. 211 (motion for judgment as a matter of law of no indirect infringement); Dkt. No. 212 (motion for judgment as a matter of law of no willful infringement). Following the close of the evidence, Kaneka filed a motion for judgment as a matter of law as to validity. Dkt. No. 222. The court construes the parties' motions as motions for judgment on partial findings under Rule 52(c). 9C Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* § 2573.1 (3d ed. 2024) ("Rule 52(c) is functionally similar to the role Rule 50 plays in a jury trial. In a nonjury trial, when the court acts as fact finder, the court may thus construe a motion for judgment as a matter of law as a motion for judgment on partial findings."). The parties' Rule 52(c) motions largely duplicate, and in some respects supplement, their proposed findings of fact and conclusions of law. All of the arguments made in the parties' motions and in their proposed findings of fact and conclusions of law are addressed in this order. References to the "opening brief" and the "reply brief" are to the parties' briefing on their proposed findings of fact and conclusions of law. The cited page numbers refer to the numbers at the bottom of each page, not the numbers in the CM/ECF header. References to the trial transcript will include the trial day ("TD1" through "TD4") and the page and line numbers of the transcript for that day. The trial transcripts can be found in docket entries 235 through 238.

nutritional supplements. *See id*. at col. 1, ll. 24–32; *id*. at col. 1, ll. 40–41 ("[S]tabilization of reduced coenzyme Q_{10} (protection of oxidation) is a highly important object."). As a method of stabilizing reduced CoQ_{10} and preventing its oxidation, the '080 patent teaches a composition of reduced CoQ_{10} that also contains reduced Coenzyme Q_9 ("CoQ_9") and/or reduced Coenzyme Q_{11} ("CoQ_{11}"), and a method of producing such a composition. *See id*. at col. 2, ll. 36–41 ("The present inventors have conducted intensive studies in an attempt to solve the above-mentioned problems and found that reduced coenzyme Q_{10} can be stabilized by the co-presence of reduced coenzyme Q_9 and/or reduced Coenzyme Q_{11}, which are analogs of reduced coenzyme Q_{10}."). Coenzymes Q_9, Q_{10}, and Q_{11} are collectively referred to as Coenzyme Q homologs ("CoQ homologs"). *See* PTX 82 at 40.

Claims 5 and 15 of '080 patent are the asserted claims in this case. Claim 5 of the '080 patent recites as follows:

> A reduced coenzyme Q_{10}-containing composition comprising reduced coenzyme Q_{10} and one or both (a) and (b):
>
> > (a) not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10} and
> >
> > (b) reduced coenzyme Q_{11}
> >
> > wherein not less than 0.01 wt % of reduced coenzyme Q_{10} is contained in the composition, and
> >
> > wherein the proportion of reduced coenzyme Q_{10} relative to the total amount of coenzyme Q_{10} is not less than 90 wt %.

Id. at col. 16, ll. 55–65.

Claim 15 of the '080 patent recites as follows:

> A method for producing a reduced coenzyme Q_{10}-containing composition, which method comprises
>
> > providing a composition comprising oxidized coenzyme Q_{10} with one or both of oxidized coenzyme Q_9 and oxidized coenzyme Q_{11}, and then

> reducing oxidized coenzyme Q_{10} and reducing one or both of oxidized coenzyme Q_9 and oxidized coenzyme Q_{11} to prepare the reduced coenzyme Q_{10}-containing composition,
>
> wherein the composition comprises reduced coenzyme Q_{10} and one or both of (a) not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10} and (b) reduced coenzyme Q_{11},
>
> wherein not less than 0.01 wt % of reduced coenzyme Q_{10} is contained in the composition, and
>
> wherein the proportion of reduced coenzyme Q_{10} relative to the total amount of coenzyme Q_{10} is not less than 90 wt %.

Id. at col. 18, ll. 4–21.

Defendant ARN produces ingredients for nutritional supplements, including a trademarked formulation of ubiquinol known as DuoQuinol. *See* TD1 at 175:2–176:12. Defendant DFH manufactures, distributes, and sells nutritional supplements that contain DuoQuinol,[2] including CoQnol-100, CoQnol-200, Q10.1-100, and Q10.1-200 (the "accused products"). *See* PTX 6, PTX 17, PTX 53.[3] Kaneka alleges that the defendants infringe the asserted claims of the '080 patent by manufacturing, marketing, and selling the accused products.

DISCUSSION

I. Infringement

An accused product infringes a claim if it satisfies each limitation of that claim. *TEK Glob., S.R.L. v. Sealant Sys. Int'l, Inc.*, 920 F.3d 777, 784 (Fed. Cir. 2019). Kaneka has the burden of

[2] The defendants argue in their opening brief that DuoQuinol is not at issue because Kaneka presented no evidence that DuoQuinol, as a raw ingredient, infringes the asserted claims. Dkt. No. 231 at 1 n.1. Kaneka does not appear to be asserting infringement based on DuoQuinol itself, which is not sold separately from the CoQnol and Q10.1 lines of products, but is incorporated within those products as an ingredient. *See* Dkt. No. 232 at 1 n.1. To the extent that Kaneka is asserting infringement based on DuoQuinol alone, the defendants are correct that Kaneka has presented no evidence that DuoQuinol by itself infringes the asserted claims.

[3] Although the record does not contain an exhibit that shows the label for Q10.1-200, the defendants do not contest that DFH manufactures, distributes, and sells Q10.1-200.

proving infringement by a preponderance of the evidence. *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 261 F.3d 1329, 1336 (Fed. Cir. 2001).

A. Direct Infringement

Kaneka asserts that it has established direct infringement based on testing supervised by its expert, Dr. Allan Myerson, as well as testing performed by Kaneka's Quality Assurance Team ("QAT"). Dr. Myerson's testing was carried out at Curia Indiana ("Curia"), a commercial laboratory that follows the Food and Drug Administration's Current Good Manufacturing Practice testing regulations. *See* TD1 at 82:10–19; *id*. at 83:9–12. The court refers to Dr. Myerson's testing as the "Curia testing" or "Curia tests" and the testing conducted by Kaneka's Quality Assurance Team as the "QAT testing" or "QAT tests."

The defendants did not introduce evidence as to any testing they may have conducted on their accused products. Rather, they limit their noninfringement case to challenging the reliability of the Curia testing and the QAT testing.

Regarding the QAT testing, the defendants argue that reliance on that testing evidence is improper because: (1) Kaneka did not rely on the QAT testing data until the cross-examination of its corporate representative, Dr. Iwao Funahashi, at trial; (2) Dr. Myerson did not rely on those tests in his expert report;[4] (3) the QAT testing methods were undisclosed; and (4) there is a chain of custody issue with regard to the samples used in the QAT testing. *See* Dkt. No. 231 at 3–4. As explained below, the Curia testing is sufficient on its own to establish each limitation of claims 5

[4] The parties stipulated to the admission of both sides' expert reports into evidence in this case. *See* TD1 at 71:16–72:2.

and 15 of the '080 patent. It is therefore unnecessary to resolve the disputes regarding Kaneka's QAT testing.[5]

1. Claim 5 of the '080 Patent

i. Curia Testing Methodology and Results

The Curia testing process involved two types of tests to measure the concentration of compounds present in the accused products: (1) high-performance liquid chromatography using an ultraviolet detector ("HPLC-UV") and (2) liquid chromatography performed with two mass spectrometers ("LC-MS/MS"). The Curia testing process used HPLC-UV to measure the concentration of ubiquinol (reduced CoQ_{10}) and ubiquinone (oxidized CoQ_{10}) in the accused products. *See* PTX 71 at 33. The Curia testing process used LC-MS/MS to measure the concentration of CoQ_9 and CoQ_{11} in the accused products. *See* PTX 5 at 4. Both HPLC-UV and LC-MS/MS were performed on one soft gel capsule of each accused product: CoQnol-100, CoQnol-200, Q10.1-100 and Q10.1-200. *See* PTX 71 at 34, tbl. 4; PTX 5 at 4, tbl. 1.

At trial, Dr. Myerson described the HPLC-UV testing process as follows. First, a sample of a composition is "dissolve[d] . . . in a solvent." TD1 at 75:24–25. Next, the solvent mixture is "pump[ed] . . . through a column, which is packed with an absorbent." *Id*. at 76:1–3. The compounds within the composition "separate" because they "move through the column at different

[5] Kaneka points out that the QAT tests were "listed on the documents considered by Dr. Myerson in his infringement report." Dkt. No. 244 at 2 (citing page 2 of PTX 69, which is Dr. Myerson's reply expert report). That page of Dr. Myerson's report simply states that "[a] list of the materials considered in preparing this Reply Report is attached as Exhibit A." PTX 72 is that Exhibit A. Although PTX 72 lists the Second Amended Complaint—to which the QAT tests were attached as an exhibit—PTX 72 does not single out or separately refer to the QAT tests. Dr. Myerson's reply expert report does not otherwise refer to the QAT tests. *See* PTX 69. Dr. Myerson also testified at trial that he did not review the QAT test data for his report, did not include any of the QAT test data in his report, and did not base any part of his opinion on infringement based on the QAT test data. *See* TD1 at 100:2–23.

rates" based on "different affinities to the material in the column." *Id*. at 76:4–8. An ultraviolet detector then measures the absorption of ultraviolet light by the separated compound flowing out of the column, which produces a graph called a chromatogram. *See id*. at 76:9–77:19.

The x-axis of the chromatogram captures time, and the y-axis of the chromatogram captures the intensity of ultraviolet absorption by a compound. *See id*. at 77:8–15. The absorption of ultraviolet light by a compound reaches its "peak" at a specific point in time—a unique "retention time" associated with each compound—so that each curve on the chromatogram can be identified with the compound being measured. *See id*. at 92:13–93:20. The area under the curve, which Dr. Myerson sometimes referred to as "area of the peak" or "peak area," is related to the concentration of a compound. *See id*. at 76:14–77:17. One representation of that relationship is the "column performance factor," also referred to as the "column performance coefficient." *See* PTX 71 at 35–36.

To derive the column performance factors for ubiquinol and ubiquinone, Curia ran "standard" solutions of known concentrations through the column and obtained chromatograms for the ubiquinol and ubiquinone in those solutions. *See* TD1 at 85:6–86:17. The concentration of ubiquinol in the ubiquinol standard was 50 mg per 100 ml; the concentration of ubiquinone in the ubiquinone standard was 20 mg per 100 ml. *Id*. Curia divided those concentrations by the respective areas under the curve on the chromatogram and calculated the column performance factors to be 9.841×10^{-7} for ubiquinol and 6.57×10^{-7} for ubiquinone. *Id.; see also* PTX 71 at 35–36.

Once the column performance factors were known, it was possible to calculate the concentrations of ubiquinol and ubiquinone in the accused products based on the area under the curve shown on the chromatograms. That is, the concentration of either compound in each softgel

capsule of the accused products was the product of multiplying the area under the curve with the column performance factor, further multiplied by one hundred.[6] *See* TD1 at 87:17–88:12; PTX 71 at 37–40. Curia then calculated the percentage of ubiquinol relative to the total amount of CoQ_{10} by dividing the ubiquinol concentration by the sum of the ubiquinol and ubiquinone concentrations. *See* TD1 at 88:8–12; PTX 71 at 33.

Dr. Myerson explained that LC-MS/MS testing entails steps additional to those for HPLC-UV testing. After a solvent mixture is created and the compounds are separated in the HPLC column, the liquid is converted into a gas and then ionized. *See* TD1 at 78:4–19. The ionized gas is passed through two mass spectrometers and then through a detector, which allows the identification of compounds that are present in very small amounts in the solvent mixture. *See id*.

The HPLC-UV testing conducted by Curia determined that ubiquinol (*i.e.*, reduced CoQ_{10}) was present in each of the four accused products. PTX 71 at 37–40 (finding the concentration of ubiquinol in the accused products to be 82.46 mg/softgel, 161.28 mg/softgel, 58.64 mg/softgel, and 58.45 mg/softgel in each of the products, respectively). In particular, the HPLC-UV testing found that the weight percentage of ubiquinol relative to total CoQ_{10} exceeded 90% for each accused product, with ubiquinol comprising of 99.64%, 99.70%, 100%, and 99.62% of the total amount of CoQ_{10}. *Id.*; *see also* TD1 at 95:18–20 (Dr. Myerson's testimony that "all of the samples had 99.62 percent ubiquinol or greater."). The LC-MS/MS testing conducted by Curia found reduced CoQ_{11} present in each of the accused products. PTX 5 at 4, tbl. 2; *see also* TD1 at 92:11–93:20.

[6] The product of multiplying the area under the curve with the column performance factor was in units of milligrams per milliliter. To account for the fact that each softgel capsule of the accused products was dissolved in a 100 mL solution, the Curia testing multiplied the initial calculation of the concentration by one hundred to arrive at the number of milligrams per softgel capsule. *See* TD1 at 118:11–121:8.

ii. Infringement of Claim 5

The Curia tests results establish infringement of each limitation of claim 5.

The first limitation of claim 5—"a reduced CoQ_{10}-containing composition"—is met. The parties do not dispute that the accused products contain ubiquinol (*i.e.*, reduced CoQ_{10}). The product labels state that the accused products contain ubiquinol, which the Curia testing confirmed. *See* PTX 17; PTX 53; PTX 6.

The second limitation of claim 5—"one or both . . . (a) not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10} and (b) reduced coenzyme Q_{11}"—is met. As Dr. Myerson explained, the second limitation can be satisfied by (b) alone, and the Curia testing found reduced CoQ_{11} in all the accused products. *See* TD1 at 95:21–96:7.

The third limitation of claim 5—"wherein not less than 0.01 wt % of reduced coenzyme Q_{10} is contained in the composition"—is met. The Curia testing found between 58.45 and 161.28 milligrams of ubiquinol in each softgel capsule of the accused products. Although the defendants argue that this limitation is not met because the HPLC-UV testing did not establish the mass of the softgel capsules, *see* Dkt. No. 231 at 15, weighing the softgel capsules was not necessary. Dr. Myerson testified at trial that for 100 milligrams of ubiquinol to constitute *less* than 0.01 percent of the capsule's weight, the capsule "would have to weigh a kilogram." TD1 at 95:7–15; *see also* PTX 17; PTX 53. And it was evident that each softgel capsule, intended to be swallowed whole, weighed significantly less than a kilogram (2.2 pounds).[7] The amount of ubiquinol that the Curia testing found in each softgel capsule necessarily constituted more than 0.01 percent of the softgel capsule's weight.

[7] It follows that for 50 mg of ubiquinol to constitute less than 0.01 percent of the each softgel capsule's weight, the softgel capsule would have to weigh a half kilogram, or 1.1 pounds—which also was quite clearly not the case.

The fourth limitation of claim 5—"wherein the proportion of reduced coenzyme Q_{10} relative to the total amount of coenzyme Q_{10} is not less than 90 wt %"—is met. The Curia testing found that the accused products had 99.62 percent or more ubiquinol relative to the total amount of CoQ_{10} (*i.e.*, the sum of the ubiquinol and the ubiquinone).

Accordingly, the Curia testing establishes direct infringement of claim 5 of the '080 patent.

2. Challenges to the Curia HPLC-UV Testing Methodology

The defendants presented no affirmative evidence of noninfringement based on any testing they may have conducted. They focus instead on the asserted inadequacies of the Curia testing methodology—specifically the HPLC-UV testing—to argue that Kaneka has not satisfied its burden to prove infringement. *See* Dkt. No. 231 at 5–16. The defendants do not challenge the methodology used in the LC-MS/MS testing. *See id*.

The defendants argue that the Curia HPLC-UV testing protocol was unreliable because: (1) it did not use a multipoint calibration curve; (2) the determination of reduced CoQ_{10} content was improperly extrapolated from a single-point calibration curve; (3) the retention time of reduced CoQ_{10} in the accused products did not match that of the ubiquinol standard; (4) tests were performed on only one sample of each accused product; and (5) the softgel capsules were not weighed, and it was unclear how many softgel capsules were used for the tests.

None of the defendants' critiques is sufficient to establish that Kaneka failed to satisfy its burden of proof.

i. Issues Related to Curia's "Single-Point Calibration Curve"

As explained above, the Curia HPLC-UV testing calculated column performance factors using ubiquinol and ubiquinone standards of known concentrations. *See supra*, Section I.A.1.i. The ubiquinol and ubiquinone concentrations in the samples of accused products were then

calculated based on the column performance factors. Although the Curia LC-MS/MS testing used calibration curves for CoQ_9 and CoQ_{11}, *see* PTX 5 at 17–18, the Curia HPLC-UV testing did not use a calibration curve. A "calibration curve" in the context of HPLC-UV testing is a straight line derived from linear regression, where the x value of any point on the line reflects the concentration of a compound and the y value reflects the area under the curve on the chromatogram (*i.e.*, "the peak area"). *See* DTX 60 at 7, 14. Thus, once the area under the curve on the chromatogram is known, the calibration curve provides the corresponding concentration of the compound. *See* TD1 at 94:6–11. Dr. Myerson testified at trial that he used "column performance factors . . . instead of using [a] calibration line" in the Curia HPLC-UV testing,[8] *see* TD1 at 135:16–19, and Dr. Taylor also testified at one point that there was no calibration curve in the Curia HPLC-UV testing, *see* TD2 at 83:1–2.

In their Rule 52(c) motion, the defendants argue that the Curia HPLC-UV testing is unreliable because it "does not contain a calibration curve." Dkt. No. 210 at 2. In their opening brief, however, the defendants criticize the methodology of the Curia HPLC-UV test for using a "single-point calibration curve." *See* Dkt. No. 231 at 6 (internal quotation marks omitted); *id*. at 8 (the defendants' diagram of the single-point calibration curve). The defendants' characterization relies on the portion of Dr. Myerson's cross-examination, where defense counsel asked, "[I]t's true you did a calibration line, you just did it with a single point, correct?" and Dr. Myerson agreed that using a column performance factor derived from a single standard was "effectively like a single-point calibration," or rather, "two points" calibration where the second point on the

[8] The record contains references to both "calibration curves" and "calibration lines," which mean the same thing for purposes of the defendants' argument. *See* Dkt. No. 231 at 6 n.4 ("Because the 'single-point' calibration curve passes through the origin, the equation of that line would be y = mx, where 'm' is the slope of the 'single-point' calibration curve."). The court refers to "calibration curves" to be consistent with the parties' more frequently used terminology.

calibration line is the origin (*i.e.*, the zero point for both the x and y axes). *See* TD1 at 135:20–136:4. Dr. Myerson explained that the calibration line would go through the origin because if a solution contained no CoQ_{10}, there would be no corresponding area under the curve on the chromatogram. *See id*. at 138:2–13. For the sake of clarity and consistency, I refer to Curia's column performance factor-based methodology as using a single-point calibration curve.

The defendants argue that "a multi-point calibration curve is the industry-standard way" and that the Curia HPLC-UV testing results relying on a single-point calibration curve are "highly suspect and unreliable." Dkt. No. 231 at 5–7. The defendants also argue that the Curia HPLC-UV testing "could not have reliably or accurately measured the concentration of reduced CoQ_{10}" in the accused products because the accused products contained higher concentrations of ubiquinol than the standard. *Id*. at 7–9. Both arguments are unpersuasive.

The difference between what the defendants characterize as single-point calibration and multipoint calibration lies in the number of testing standards that are used to create the calibration curve. The defendants' expert, Dr. Richard Taylor, testified at trial that a multipoint calibration curve uses multiple standards "to cover a large enough range of concentration so that any unknown samples that you're going to compare . . . will fall between the high[est] and lowest point."[9] *See*

[9] At oral argument on the post-trial briefing, Kaneka argued that Dr. Taylor's testimony on a multipoint calibration curve was not disclosed in his expert reports. The defendants argued that Dr. Taylor's trial testimony related directly to paragraphs 54 through 58 of his expert rebuttal report and that he used the term "standard curve" in his report to mean multipoint curve. *See* PTX 68 at 22 ("The standard is analyzed at various concentrations to develop a *standard curve* that can then be used to calculate the concentration of the compound in a sample being analyzed.").

This issue was addressed at trial. Kaneka argued that what Dr. Taylor "says in the report strictly is limited to the lack of a calibration curve" and objected to questions going beyond that limit. *See* TD2 at 67:20–68:7. The defendants responded that Dr. Taylor discussed "standard calibration curve protocol and references to that point" in his report, and the court allowed questions directed "to what a standard calibration is." *See id*. at 68:11–69:18. Dr. Taylor's testimony about calibration curves makes clear that what he referred to as a "standard curve" in

TD2 at 70:8–21. Dr. Taylor, for instance, preferred to use five testing standards. *See id*. Referring to the concentration of the single standard used in the Curia HPLC-UV testing, Dr. Taylor testified that there was only a "single point on their so-called calibration curve." *See id*. at 88:3–6. To be clear, the defendants do not argue that the measurement of that single point—*i.e.*, the area under the curve for the ubiquinol standard with a concentration of 50 mg per 100 ml—was inaccurate or unreliable. Instead, the defendants challenge the reliability of creating a calibration curve based only on that point and the origin, and then extrapolating on the calibration curve beyond that single point.

In arguing that a multipoint calibration curve is the "industry-standard way," the defendants rely on the testimony of Dr. Taylor and two studies. *See* Dkt. No. 231 at 5–6. Dr. Taylor testified at trial that he did not regard using a column performance factor based on a single standard as an "accepted methodology" and that he "would never use it." *See* TD2 at 64:8–65:8. The two studies that the defendants cite also used multipoint calibration curves. *See* DTX 58 at 4 ("Quantification is performed using a CoQ_{10} external standard and a 5-point calibration curve."); DTX 60 at 5 ("A 5-point calibration curve was created on 3 separate days using the following concentrations of CoQ_{10}: 0.125, 0.1, 0.075, 0.050 and 0.025 mg/mL.").

While Dr. Taylor has significant experience in HPLC technology, *see* TD2 at 53:4–54:2, it is not evident from his testimony and experience that a multipoint calibration curve is the only way to produce reliable calculations of the concentrations of unknown substances in a sample. Dr. Myerson, who also has significant experience in this field, testified that it was appropriate to

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his report is the same thing that the parties refer to as a "multipoint calibration curve" in their post-trial briefing—namely, linear regression based on more than one concentration. *See id*. at 69:20–74:6. The court also received letter briefing on this issue during trial and ultimately overruled Kaneka's objection to Dr. Taylor's testimony on calibration. *See* Dkt. Nos. 208, 209; TD3 at 6:2–18.

use column performance factors, as he did, based on a single standard. *See* TD1 at 67:25–68:10; *id*. at 165:6–21. Specifically, Dr. Myerson testified that although multipoint calibrations are "quite common," they are "[j]ust another way of doing things," and that he did not always use a multipoint calibration curve in testing done for his peer-reviewed research papers. *See id*. at 165:22–166:10. Nor is Dr. Myerson's testimony inconsistent with the studies in the record, which demonstrate only that a multipoint calibration curve was used in those studies, not that a multipoint calibration curve is necessary to produce reliable results. If anything, the calibration curves in those studies suggest that the slope of the regression line would not have changed significantly even if fewer standards had been used. *See, e.g.,* DTX 44 at 110; TD2 at 70:25 (Dr. Taylor's testimony that the calibration curves in DTX 44 have "very good linearity").

As for the unreliability of extrapolations, the defendants cite the testimony of Dr. Taylor, who testified at trial that there is no guarantee of accurate measurements when the concentration in a sample is "greater than the end point of the standard calibration curve." *See* TD2 at 79:16–80:4. That is, Dr. Taylor testified that calibration curves are "not going to keep going straight out," but will "level off because you're saturating the system," so that you "want to only measure in a linear portion of the standard curve." *See id*. at 75:12–24. Thus, according to Dr. Taylor, Curia's measurements of ubiquinol were unreliable because they all purported to measure a concentration of ubiquinol greater than the concentration of ubiquinol in the single standard that was used (50mg/100ml). *See id*. at 91:1–92:19.

Dr. Taylor, however, did not testify as to when that point of saturation would occur for ubiquinol, such that a calibration curve for ubiquinol would level off and no longer be linear. He spoke only of what would theoretically happen to the calibration curve in DTX 44—a research paper not about the accused products—when asked what the concentration of alpha-tocopherol

would be at a "peak height [of] 500." *See id*. at 71:6–75:24 (discussing Figure 2 in DTX 44). There is no evidence in the record showing that the calibration curve would not be linear for the range of concentrations of ubiquinol measured by the Curia HPLC-UV testing.

The defendants also challenge the reliability of the Curia HPLC-UV testing by arguing that Dr. Myerson never confirmed whether a "blank" solution without any ubiquinol would produce no ubiquinol peak. *See* Dkt. No. 231 at 6. But that argument, too, is unpersuasive. Dr. Myerson testified only that he did not recall whether blank solutions were run. *See* TD1 at 139:24–25. And although the defendants cite a research paper (DTX 50) as showing calibration curves that do not pass through the origin, Dr. Myerson explained that those curves did not go through the origin because that study was "using a method of standard additions," which was not the method used in the Curia HPLC-UV testing. *See id*. at 152:7–153:14. A different study that the defendants introduced into evidence showed calibration curves that passed through the origin. *See* DTX 44 at 110.

Accordingly, the use of a single-point calibration curve does not establish that Kaneka failed to satisfy its burden of proof.

ii. Retention Time of Ubiquinol

As explained above, each chemical compound has a unique retention time. The defendants contend that the Curia HPLC-UV testing was "indisputably flawed" based on what they view as an unacceptably large difference between the average retention time of ubiquinol in the accused products and the retention time of ubiquinol in the ubiquinol standard.[10] Dkt. No. 231 at 9–13.

[10] For support, the defendants cite Dr. Taylor's testimony about the differences in ubiquinol retention times. Dkt. No. 231 at 10 (citing TD2 at 102:20–103:1; *id*. at 106:1–110:10). Portions of Dr. Taylor's testimony that the defendants cite were excluded at trial. *See* TD2 at 102:20–103:1 (cited testimony); *id.* at 103:3–105:24 (objection and ruling); *see also* TD3 at 6:19–

The defendants calculate the percentage error from the standard retention time to be 4.08 percent, based on the difference of 0.63 minutes. *Id.* at 12.

The defendants rely on Dr. Taylor's testimony that the retention time for a particular compound should not vary by more than a percentage point or two, *see* TD2 at 61:2–6. The defendants also cite an article presented at trial, DTX 60 ("Orozco"), for the proposition that an HPLC system "is considered suitable if the retention times of the peaks do not deviate more than 0.5 min." DTX 60 at 5.

Kaneka responds that the defendants are impermissibly presenting conclusions that went beyond the scope of Dr. Taylor's report, and that Orozco, the only other support the defendants cite for their argument, does not stand for the proposition for which the defendants rely on it. *See* Dkt. No. 244 at 11–12. Kaneka argues that the Orozco article does not purport to describe a generally accepted standard, but addresses only the specific method used in that study, which the article describes as requiring that the retention times should not deviate by more than 0.5 minutes. Kaneka also points out that Orozco provides the "approximate retention times" for CoQ_{10} as ranging from 3.8 to 4.0 minutes, *see* DTX 60 at 5, so that the allowed deviation of 0.5 minutes must be read in the context of that range. According to Kaneka, "a 0.5 minute deviation for the specific HPLC test described in Orozco equates to a 12.5% deviation from the high end of the retention time range for reduced coenzyme Q10." Dkt. No. 244 at 12.

The defendants' retention-time challenge to the Curia HPLC-UV testing methodology was not addressed in the expert reports in this case. Because Dr. Taylor did not discuss the differences in retention times in his expert report, *see* PTX 82, Dr. Myerson never had the opportunity to

7:9 (ruling after the parties filed letter briefs). In light of the court's ruling that Dr. Taylor could testify that there was a difference in the peaks, but not what that difference might represent, the court will not consider the excluded testimony found at TD2 at 102:20–103:1.

respond, *see* PTX 83. Additionally, because there was no discussion of the retention time issue in his expert report, Dr. Taylor was permitted to testify only that there was a difference in the peaks at trial. *See* TD3 at 6:19–7:9. As a result of the limited scope of the expert reports, the court is left with only Dr. Taylor's testimony that for any specific compound "the retention time really shouldn't vary more than a percentage point or two," *see* TD2 at 61:2–6, and a statement in the Orozco article that the retention times of the peaks should not deviate by more than 0.5 minutes for that specific HPLC protocol, *see* DTX 60 at 5. Given the lack of expert testimony on this issue, the inconsistencies between Dr. Taylor's admitted testimony and Orozco (which permits a deviation of up to 12.5 percent in retention times), and the fact that the deviation in ubiquinol retention times in the Curia HPLC-UV testing was only 4.08 percent, the record does not support the defendants' contention that the Curia testing was "indisputably flawed."

Accordingly, the differences in the retention times for ubiquinol do not establish that Kaneka failed to meet its burden of proof.

iii. Use of a Single Sample

The defendants next argue that the Curia HPLC-UV testing is unreliable because it did not analyze multiple samples of each accused product. *See* Dkt. No. 231 at 13–14. For support, the defendants rely on Dr. Taylor's testimony as to the impropriety of testing only one sample, *see* TD2 at 62:21–63:3, as well as on journal articles in which the authors ran multiple tests on a sample, using from three to as many as fifteen replicates for a sample, *see* DTX 44 at 111–112; DTX 50 at 249; DTX 58 at 11, tbl. 1; DTX 60 at 6.

Relatedly, the defendants argue that the third limitation of claim 5—"wherein not less than 0.01 wt % of reduced coenzyme Q_{10} is contained in the composition"—is not satisfied because Curia's HPLC-UV testing protocol does not establish how many softgel capsules were used in the

testing procedure. Dkt. No. 231 at 14–16. It is evident, however, that the Curia HPLC-UV testing was performed on a single softgel capsule (and thus one sample) for each of the four accused products. Dr. Myerson testified that if more than one softgel capsule had been tested, there would have been additional chromatogram results for each additional softgel capsule, which was not the case. *See* TD1 at 114:9–23. The mere fact that the testing protocol refers to "[s]ample softgel*s*" and "capsule*s*" does not plausibly suggest, as the defendants argue, that multiple softgels were used to prepare each sample. *See* PTX 71 at 33 (emphasis added). Table 4 of the protocol refers to "softgel" in the singular in describing the samples. *See id*. at 34. Moreover, the defendants do not argue that the measured amounts of ubiquinol in each sample are inconsistent with testing only one softgel capsule. I therefore find that the Curia HPLC-UV testing analyzed a single sample of each accused product in the form of a single softgel capsule.

The evidence in the record also does not show that testing only a single sample produced unreliable results. Dr. Taylor's testimony on this subject is limited to one word:

> Q: Okay. And the other thing I asked Dr. Myerson about yesterday was how many softgels were used for each analysis. I think he said that one was used for each analysis because there's one chromatogram from for each sample. But even if we're assuming that correct, is that the proper number of samples to use for an analysis like this?
>
> A: No.

TD2 at 62:21-63:3. Absent any further explanation, Dr. Taylor's conclusory statement is not enough to overcome Dr. Myerson's testimony that it was unnecessary to run multiple tests on the accused products because the results of the tests were all well above 90 weight percent ubiquinol compared to overall CoQ_{10}. *See* TD1 at 114:24–117:22 ("[I]f the results had shown 90.1 percent ubiquinol . . . you might wonder, if you ran multiple softgels, whether some of them would be 89.9 percent ubiquinol because you're looking for 90 percent. We're looking for 90 percent and we're getting results of 99 percent, it's certainly adequate."). Dr. Myerson explained that, while his

standard practice in his academic laboratory is to run a sample at least twice, it was appropriate for Curia to run one sample per product in light of those initial results.[11] *Id.* at 127:9–128:19. Moreover, the fact that the Curia testing methodology differed from the more extensive procedures used in research for peer-reviewed publications does not suggest that the Curia results are inaccurate or insufficient for Kaneka to meet its burden of establishing infringement by a preponderance of the evidence.

Accordingly, the use of a single sample does not establish that Kaneka failed to satisfy its burden of proof.

iv. Discrepancies Between the Product Labels and Curia's Testing

In their reply brief, the defendants raise an additional argument for the first time: that the discrepancies between Curia's measurement of ubiquinol in the accused products and the amount of ubiquinol indicated on the product labels demonstrate that the Curia HPLC-UV testing is unreliable. *See* Dkt. No. 240 at 9–10. That is, the amount of ubiquinol that Curia measured in each softgel capsule of the accused products was lower than what was stated on the product labels. *See id*. at 9. The defendants argue that "[n]either Kaneka, nor Curia testing itself, nor Dr. Myerson explain[ed] why Curia's analysis produced results with a deviation that is this significant," and that "such significant deviation is highly probative of the unreliability of its results." *Id*. at 10.

[11] The defendants suggest in a footnote that this case is like *Indivior Inc. v. Mylan Technologies Inc.*, 298 F. Supp. 3d 775 (D. Del. 2018), *aff'd sub nom. Indivior Inc. v. Dr. Reddy's Lab'ys, S.A.*, 930 F.3d 1325 (Fed. Cir. 2019). In *Indivior*, the district court concluded that the evidence that was used to establish infringement was flawed because the plaintiffs' expert had used one sample (or at most two samples) to create a slope calculation, and another expert had testified that three samples are required for statistical significance. *Id.* at 788–89. Moreover, the plaintiffs in that case did not dispute that the calculations based on fewer than three samples were not statistically significant. *See id*. at 788. In this case, however, there was no evidence that multiple samples or tests per sample were necessary, and Dr. Myerson specifically testified that using only one sample was adequate for purposes of his infringement analysis, *i.e.*, determining whether the proportion of ubiquinol to the total amount of CoQ_{10} was greater than 90 percent.

Because the defendants did not raise this argument in their opening brief, Kaneka had no opportunity to respond. But even if the defendants had not waived the argument on that basis, it fails on the merits. Simply, the defendants cite no evidence to show that the discrepancies are the result of unreliable testing by Curia, ruling out other possibilities such as issues with manufacturing and/or product labeling. The defendants, for example, do not cite results of their own testing to establish that the amount of ubiquinol in samples of the accused products should match what is stated on the labels. Moreover, the defendants offer no explanation as to why discrepancies in the amount of ubiquinol matter, when the limitations in the asserted claims are concerned with the relative weight percentage of ubiquinol exceeding a certain minimum, not its amount as an absolute value. If anything, the Curia HPLC-UV testing established each minimum weight percentage limitation despite the smaller amounts of ubiquinol it measured.

Accordingly, the defendants' argument based on the discrepancies from the label is both waived and unavailing on the merits.

v. Wavelength for Testing

At trial, the parties explored the issue of the proper wavelength to use in an HPLC-UV test measuring the amount of ubiquinone in a sample. In accordance with his expert report, Dr. Taylor testified that the level of ubiquinone measured by Curia was unreliable because ubiquinone should be measured using an ultraviolet source having a wavelength of 275 nm, yet Curia used a source having a wavelength of 290 nm to measure both ubiquinone and ubiquinol. *See* TD2 at 218:14–21; PTX 68 ¶ 58. But when asked about the fact that a wavelength of 210 nm was used to measure ubiquinone in a prior art reference, *Distribution and Redox State of Ubiquinones in Rat and Human Tissues* by Fredrik Åberg et al. ("Åberg"), Dr. Taylor acknowledged that 275 nm is not the only wavelength at which ubiquinone can be measured. *See* TD2 at 232:22–233:25; DTX 26.

The defendants did not make an argument based on the trial testimony regarding wavelengths in their opening brief, but Kaneka preemptively addressed that subject in its opening brief. Kaneka argues that there was no evidence at trial that Curia's failure to use a wavelength of 275 nm makes the Curia HPLC-UV results unreliable, as there was no treatise, textbook, or other authority cited for that proposition, and because the defendants relied heavily on the Åberg reference, which did not use a 275 nm wavelength. *See* Dkt. No. 232 at 20. Kaneka also cites Dr. Myerson's reply report, in which Dr. Myerson responded to paragraph 58 of Dr. Taylor's report by stating the following:

> Dr. Taylor opines that ubiquinol and ubiquinone should be measured at different wavelengths. This is incorrect as HPLC on a sample of a mixture is performed at a single wavelength. In addition, the column performance and ubiquinol and ubiquinone coefficients obtained demonstrated that good separation and column performance[.] The wavelength of the measurement is of little consequence since adequate sensitivity and specificity were demonstrated. Thus the Curia analysis was appropriate.

PTX 69 ¶ 50.

The defendants respond with several arguments. *See* Dkt. No. 240 at 13–14. First, the defendants argue that other scientific publications in the record used an ultraviolet light source with a wavelength of 275 nm to measure ubiquinone. *See* DTX 44 at 108–109; DTX 50 at 248; DTX 58 at 1; DTX 60 at 2. Second, the defendants argue that Kaneka used a source with a wavelength of 275 nm for detection of ubiquinone in its New Dietary Ingredient Notification submitted to the FDA. *See* DTX 27 at 81. Third, the defendants argue that Åberg's use of a source with a wavelength of 210 nm was acceptable because Dr. Taylor testified that ultraviolet light with the shorter wavelength would "pick up everything."[12] *See* TD2 at 233:5–18.

[12] The defendants also argue that if Kaneka is contending that it is improper to use a wavelength of 210 nm to detect CoQ homologs, then the '080 patent is invalid under 35 U.S.C. § 112, because the '080 patent utilized a wavelength of 210 nm for the measurements used to

Although it appears that a wavelength of 275 nm is frequently used to measure oxidized CoQ homologs, nothing in the evidence indicates that the use of a wavelength of 290 nm made the results of the Curia HPLC-UV testing unreliable. It is unclear what effect the defendants believe using a wavelength of 290 nm would have had on the results. Dr. Taylor testified that using a wavelength of 290 nm "can make a significant difference on . . . any kind of quantifications that you are doing," but he did not elaborate on that assertion. *See* TD2 at 218:14–21. Moreover, as noted, Dr. Taylor acknowledged that 275 nm is not the only wavelength at which ubiquinone can appropriately be measured. *See* TD2 at 232:22–233:25. Considering Dr. Myerson's statement that other indicators in the Curia HPLC-UV testing demonstrate that "[t]he wavelength of the measurement is of little consequence" in this case, PTX 69 ¶ 5, I find no reason to discredit Kaneka's testing based on the use of a wavelength of 290 nm in the ultraviolet detector.

3. Claim 15 of the '080 Patent

Claim 15 of the '080 patent recites the same composition as claim 5, with an additional method requirement:

> A method for producing a reduced coenzyme Q_{10}-containing composition, which method comprises providing a composition [with the requirements of claim 5], and then reducing oxidized coenzyme Q_{10} and reducing one or both of oxidized coenzyme Q_9 and oxidized coenzyme Q_{11} to prepare the reduced coenzyme Q_{10}-containing composition[.]

PTX 1 at col. 18, ll. 6–12.

DFH's instructions for producing ubiquinol stated: "Making ubiquinol—we are converting from one chemical form of CoQ_{10} to another. To do that, air (oxygen) must be avoided to prevent reversing this reaction during the 5 day hold time." PTX 18 at 1. Those instructions establish that

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establish that Kaneka possessed those CoQ homologs. *See* Dkt. No. 240 at 14. Kaneka does not appear to be arguing that it is improper to use a wavelength of 210 nm, but rather that 275 nm is not the only wavelength that can be used. *See* Dkt. No. 232 at 20.

the method limitation in claim 15 is satisfied. Dr. Myerson explained that DFH manufactures its products by "begin[ning] with oxidized coenzyme Q_{10} and reduc[ing]" the compound. *See* TD1 at 96:15–23. He explained that because the accused products "contained reduced coenzyme Q_{11} at the end, coenzyme Q_{11} had to be there at the beginning, and it had to be in the oxidized form." *Id*. at 97:4–8. When asked why CoQ_{11} had to be present in an oxidized form at the beginning, Dr. Myerson responded that it was "[b]ecause [the Q_{11} is] unstable, just like the Q_{10} is, and the Q_{10} is in the oxidized form." *Id*. at 97:19–23.

The only argument that the defendants make regarding the limitation of oxidized CoQ_{11} in claim 15 is a passing reference made in the background section of their argument on patent invalidity. Dkt. No. 231 at 18. The defendants assert that "both Dr. Taylor and the inventor of the '080 Patent, Dr. Ueda, testified about the biological processes, including the fermentation employed by Kaneka, that led to the necessary occurrence of CoQ_{11} . . . a fact for which the experts seemingly agree; and if they do not, Kaneka cannot prove its infringement case, at least as to claim 15, because Kaneka established no facts to show that Defendants 'provid[ed] a composition comprising oxidized coenzyme Q_{11}.'" *Id*. But what process Kaneka used is irrelevant to the question whether DFH's instructions, together with Dr. Myerson's testimony, demonstrate that DFH infringed claim 15 by providing a composition that initially contained oxidized CoQ_{11}.

I find Dr. Myerson's testimony to be both credible and sufficient to establish infringement of claim 15.

B. Induced Infringement

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). "A defendant is liable for induced infringement under § 271(b) if the defendant took certain affirmative acts to bring about the commission by others of acts of infringement and

had knowledge that the induced acts constitute patent infringement." *Roche Diagnostics Corp. v. Meso Scale Diagnostics, LLC*, 30 F.4th 1109, 1118 (Fed. Cir. 2022) (quoting *TecSec, Inc. v. Adobe Inc.*, 978 F.3d 1278, 1286 (Fed. Cir. 2020)) (internal quotation marks omitted). Importantly, the defendant's "knowledge of the patent in suit" is necessary but not sufficient to establish induced infringement: "liability for induced infringement can only attach if the defendant knew of the patent and knew as well that the induced acts constitute patent infringement." *See Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 639–40 (2015) (quoting *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011)) (internal quotation marks omitted). While knowledge of infringement must be proved to establish induced infringement, knowledge of infringement "can be inferred from circumstantial evidence." *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 824 F.3d 1344, 1347 (Fed. Cir. 2016).

"[W]illful blindness can satisfy the knowledge requirement for active inducement under § 271(b) . . . even in the absence of actual knowledge." *Id.* at 1347 (citing *Global-Tech*, 563 U.S. at 769). Willful blindness has "two basic requirements: (1) The defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact." *Global-Tech*, 563 U.S. at 769. Willful blindness is thus a standard that "surpasses recklessness and negligence." *Id.* ("By contrast, a reckless defendant is one who merely knows of a substantial and unjustified risk of such wrongdoing, and a negligent defendant is one who should have known of a similar risk but, in fact, did not.") (internal citations omitted).

Kaneka argues that ARN induced DFH to infringe the '080 Patent. Dkt. No. 232 at 21. Kaneka's arguments on induced infringement hinge on the knowledge and intent of "Dr. Barrie Tan, who owns half of ARN with his wife . . . and is the Chief Medical Officer of DFH." *Id.*; *see*

also TD1 at 176:13–24. Dr. Tan first developed DuoQuinol at ARN, then shared the formula for DuoQuinol with DFH to further develop DuoQuinol at scale. *See* TD1 at 179:4–180:17.

It is undisputed that Dr. Tan knew about the '080 Patent. *See* Dkt. No. 211 at 3 (the defendants' concession that "[a]t most, Kaneka has proved that Dr. Barrie Tan was generally aware of the '080 Patent."); *see also* TD1 at 194:2–4 (deposition designations of Dr. Tan). As Kaneka concedes, however, knowledge of the patent alone is insufficient to establish induced infringement. *See* Dkt. No. 232 at 20; *see also Commil*, 575 U.S. at 640 (rejecting the argument that "only knowledge of the patent is required for induced infringement"). Kaneka thus argues that "Dr. Tan's knowledge of his own invention as well as the '080 Patent, and . . . Defendants[']' [choice] not to rely on the opinion letter he received [from his counsel] at trial provide circumstantial evidence to warrant a finding that he knew his product was infringing." *Id*. at 22. That argument fails.

In the deposition designations that Kaneka played at trial, Dr. Tan was asked whether he "[came] to a decision about whether or not . . . DuoQuinol possibly infringed the '080 patent" after he became aware of the patent. *See* TD1 at 194:9–13. Dr. Tan replied that he could not answer the question because it was "a legal question and [he] [was] not an attorney." *See id*. at 194:14–18. Dr. Tan then acknowledged that he asked his patent attorney to "determine whether or not DuoQuinol infringed" the '080 Patent, and that his attorney "provide[d] a written response" to that question. *See id.* at 194:21–195:24. In the deposition designations played at trial, however, Dr. Tan was not asked about the contents of his attorney's letter, nor did he volunteer to disclose its contents. *See id*. at 195:19–196:10. And the defendants have not otherwise presented the letter as evidence at trial.

Kaneka asks this court to infer from the defendants' non-production of the attorney's letter that Dr. Tan learned that DuoQuinol was infringing. As the defendants point out, however, that inference is barred by both statute and precedent. Dkt. No. 240 at 3. Section 298 of the Patent Act provides, in pertinent part, that "the failure of the infringer to present [the] advice [of counsel] to the court or jury[] may not be used to prove that the accused infringer willfully infringed the patent or that the infringer intended to induce infringement of the patent." 35 U.S.C. § 298. Likewise, the Federal Circuit has barred "[t]he adverse inference that an opinion was or would have been unfavorable, flowing from the infringer's failure to obtain or produce an exculpatory opinion of counsel." *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1344 (Fed. Cir. 2004) (en banc).[13] I therefore decline to infer from the non-production of the letter from Dr. Tan's attorney—whether on its own or together with other circumstantial evidence—that Dr. Tan knew his actions in creating DuoQuinol were infringing. Kaneka does not contend, and I do not find, that Dr. Tan's "knowledge of his own invention as well as the '080 Patent" is sufficient to establish that he actually knew his use was infringing. *See* Dkt. No. 232 at 22.

[13] Kaneka does not address these authorities in its reply brief, even as it continues to rely on the defendants' non-production of Dr. Tan's letter as circumstantial evidence of Dr. Tan's belief that the DuoQuinol formula infringed the '080 Patent. *See* Dkt. No. 244 at 20. Kaneka ignores section 298 altogether. As for *Knorr-Bremse*, Kaneka cites the case (without explanation) as actually supporting its argument that "considering the totality of the circumstances, willfulness has been established." *See id*. Kaneka appears to be relying on the holding in *Knorr-Bremse* that "[d]etermination of willfulness is made on consideration of the totality of the circumstances," 383 F.3d 1337 at 1342. But that holding is unrelated to the express prohibition elsewhere in the court's opinion in that case against drawing adverse inferences from non-production of an opinion of counsel, which is contrary to Kaneka's position regarding the attorney's letter.

Although Kaneka does not argue in its proposed findings of fact and conclusions of law that Dr. Tan was willfully blind to the fact of DuoQuinol's infringement,[14] *see* Dkt. No. 232 at 22–24, it did so in opposition to the defendants' Rule 52(c) motion, in which the defendants argued that ARN was liable for indirect infringement, *see* Dkt. No. 242 at 4. In its opposition to the defendants' motion, Kaneka asserted that "Dr. Tan and the Defendants' actions suggest they may have deliberately avoided investigating whether their products infringed the '080 Patent, despite being aware of its existence and having received an opinion letter on the matter." *Id*. Once again, Kaneka argued that "[t]heir failure to disclose the contents of this opinion letter at trial further supports this inference." *Id*. As explained above, however, that inference is barred by statute and case law. If anything, the fact that Dr. Tan asked his counsel for an opinion letter on infringement suggests that he did not take steps to avoid learning about potential infringement. Kaneka thus failed to establish that Dr. Tan (and ARN by extension) either knew or were willfully blind to the fact that DuoQuinol infringed the '080 patent.

Kaneka separately argues that "[t]he totality of the circumstantial evidence provided in connection with ARN and DFH's interactions during the period the Accused Products were being designed and produced" establishes induced infringement. Dkt. No. 232 at 23. In particular, Kaneka relies on *Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 905 (Fed. Cir. 2014), for the proposition that "[p]roviding instructions to use a product in an infringing manner is evidence of the required mental state for inducing infringement." This argument also fails.

DataTern does not stand for the proposition that providing instructions for an infringing use is sufficient to establish induced infringement. The Federal Circuit in that case addressed only

[14] Kaneka's opening brief merely sets out the standard of willful blindness. *See* Dkt. No. 232 at 21. It makes no argument that the willful blindness standard is met in this case.

whether there was "a case or controversy of sufficient immediacy to establish declaratory judgment jurisdiction," not whether there was sufficient evidence to "establish each element" of induced infringement. 755 F.3d at 905. Moreover, *DataTern* makes clear that "the patentee must show that the accused inducer took an affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement." *Id*. at 904. Providing instructions as to an infringing use does not establish induced infringement in the absence of knowledge that the induced act constitutes infringement.[15] *See id*. ("Absent the knowledge and affirmative act of encouragement, no party could be charged with inducement.").

Accordingly, Kaneka has failed to establish induced infringement.

C. Willful Infringement

Kaneka also argues that the defendants engaged in willful infringement. *See* Dkt. No. 232 at 23–24; Dkt. No. 244 at 20. Specifically, Kaneka argues that its evidence "establishes that Dr. Tan, and thus ARN, knew about Kaneka's '080 Patent but was motivated to bring his product to market anyway—even after receiving [an] opinion from counsel that has never been shared in this litigation." Dkt. No. 232 at 24; *see also* Dkt. No. 244 at 20 ("Although this legal opinion was shared with DFH, Defendants refused to produce it in this litigation. It is clear based on the undisputed facts that, considering the totality of the circumstances, willfulness has been established.").

"To establish willfulness, a patentee must show that the accused infringer had a specific intent to infringe at the time of the challenged conduct." *Provisur Techs., Inc. v. Weber*, *Inc.*, 119

[15] Kaneka's reliance on *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 668–89 (Fed. Cir. 1988), is similarly misplaced. *See* Dkt. No. 242 at 29. *Water Technologies* predated *Global-Tech*, and while it referred to the requirement of "knowing intent," it did not require the defendant to have actual knowledge that the induced acts constitute patent infringement. *See* 850 F.2d at 668–89.

F.4th 948, 955 (Fed. Cir. 2024) (quoting *BASF Plant Sci., LP v. Commonwealth Sci. & Indus. Rsch. Org.*, 28 F.4th 1247, 1274 (Fed. Cir. 2022)). "[K]nowledge of the asserted patent and evidence of infringement is necessary, but not sufficient, for a finding of willfulness." *Id*. at 956 (quoting *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 988 (Fed. Cir. 2021)).

Kaneka has not shown that the defendants had the specific intent to infringe. As discussed above, Kaneka may not rely on an adverse inference drawn from the defendants' non-production of the letter from Dr. Tan's attorney. Kaneka cites no other evidence of the defendants' specific intent to infringe, which must go beyond simple knowledge of the existence of a patent.

Accordingly, Kaneka has failed to establish willful infringement.

II. Invalidity

The defendants argue that claims 5 and 15 of the '080 patent are invalid on several grounds: (1) the asserted claims are directed to a patent-ineligible concept under 35 U.S.C. § 101; (2) the asserted claims are anticipated and/or obvious under 35 U.S.C. §§ 102 and 103; and (3) the asserted claims are invalid for failure to comply with the written description requirement in 35 U.S.C. § 112. The defendants must prove invalidity by clear and convincing evidence. *See Microsoft Corp. v. I4I Ltd. P'ship*, 564 U.S. 91, 95 (2011); *see also IOENGINE, LLC v. PayPal Holdings, Inc.*, 607 F. Supp. 3d 464, 488 (D. Del. 2022).

A. Patentability under 35 U.S.C. § 101

The Supreme Court has established a two-step test for courts to follow in assessing patentability under section 101. At the first step, the court determines whether the patent is directed to a patent-ineligible concept, including natural phenomena. If the court determines that the claims are directed to a patent-ineligible concept, the court then determines whether the claim contains an inventive concept sufficient to transform the claim into a patent-eligible application. *See Alice*

Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 217–18 (2014); *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 72 (2012). If the claims are directed to eligible subject matter, the inquiry ends at step one. *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1360 (Fed. Cir. 2017).

It is undisputed that CoQ_9, CoQ_{10}, and CoQ_{11} are chemical compounds found in nature. *See* Dkt. No. 231 at 27; Dkt. No. 232 at 25–26. Claims 5 and 15, however, recite a composition containing those compounds in a specific combination or ratio. In their motion for summary judgment, the defendants relied on the Åberg reference to argue that there were naturally occurring combinations of "reduced CoQ_9 and reduced CoQ_{10} in amounts that fall within the ranges recited in claim 5." Dkt. No. 112 at 12. At that time, I ruled that "DFH has not established that Åberg discloses a composition containing reduced coenzymes Q_9 and Q_{10} that would satisfy the limitations of claim 5." Dkt. No. 141 at 12.

The defendants do not argue that the composition as recited in claim 5 occurs naturally.[16] *See* Dkt. No. 231 at 27–34. Instead, the defendants argue that "[a]lthough claims 5 and 15 recite certain proportions of reduced CoQ_{10} and CoQ_9 and/or CoQ_{11}, these ratios alone are insufficient to distinguish the claimed compositions from naturally occurring CoQ compositions." *Id*. at 27; *see also id*. at 31 (describing the difference between the natural occurrence of CoQ homologs and

[16] Kaneka preemptively asserted in its opening brief that the "Defendants' naturally occurring, and anticipation arguments fail as a matter of law" because those arguments rest on a "liver water content" theory of the Åberg reference, the testimony regarding which was excluded at trial. *See* Dkt. No. 232 at 3. At trial, Dr. Taylor testified that Åberg disclosed the limitation in claim 5 regarding the weight percentage of ubiquinol, based on a calculation that excluded the weight of water from the sample of the liver. *See* TD2 at 179:23–181:25. However, I excluded that testimony based on the absence of any indication that Åberg had excluded the weight of water in the testing reported in his article, together with Dr. Myerson's credible testimony that there was no indication in Åberg that water had, in fact, been excluded. *See* TD4 at 51:8–52:1. Accordingly, Kaneka is correct that the Åberg reference does not support either that the claimed composition is naturally occurring nor anticipated.

the proportions recited in claims 5 and 15 as "legally insufficient"). The defendants assert that "[c]laimed ratios of naturally occurring elements can distinguish from that which exists naturally, but only when the composition confers '*significant* utility' over that which exists naturally." *Id*. The defendants argue that "claims 5 and 15 fail to provide significant utility over the individual components themselves," citing only Dr. Myerson's testimony for support. *See id*. at 32–33 (arguing that "under step one of the *Mayo*/*Alice* test, claims 5 and 15 are directed to natural products and/or natural phenomena").

"The rule against patents on naturally occurring things is not without limits." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013). The case law in this area recognizes the need for balance between a broad prohibition on patents relating to naturally occurring things on the one hand, which risks stifling innovation because "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas," and too narrow a prohibition on the other hand, which risks "impeding the flow of information that might permit, indeed spur, innovation." *Id.* at 589–90 (citations omitted).

In *Myriad Genetics*, the Supreme Court held that merely locating genes and isolating them from the human genome does not render those genes patent eligible. 569 U.S. at 593. The court explained that, for the patent at issue, even if the act of isolation created a molecule that does not occur naturally, the claims were directed to a patent-ineligible concept because the patentee's "claim is concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule." *Id.* (emphasis omitted). The *Myriad Genetics* Court analogized that case to *Funk Brothers Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127 (1948), in which the Supreme Court found that a patent claiming a mixture of naturally

occurring strains of bacteria was not patent eligible because the patent holder had not altered the bacteria in any way. *Myriad*, 569 U.S. at 591.

The Federal Circuit's opinion in *In re Bhagat* similarly stands for the proposition that merely extracting and combining natural products—in that case, fatty acids—in a way that is indistinguishable from the way they occur in nature does not overcome section 101. 726 F. App'x 772, 778–79 (Fed. Cir. 2018). Most recently, the Federal Circuit found in *ChromaDex, Inc. v. Elysium Health, Inc.*, that compositions including isolated nicotinamide riboside were patent ineligible. 59 F.4th 1280, 1284 (Fed. Cir 2023). The court reasoned that "[t]he claimed compositions remain indistinguishable from natural milk because, other than separation from some other components, the isolated [nicotinamide riboside] is no different structurally or functionally from its natural counterpart in milk." *Id*.

On the other hand, in *Diamond v. Chakrabarty*, the Supreme Court held that a bacterium that was modified through the addition of plasmids—the addition of which rendered the bacterium capable of breaking down crude oil—was patentable subject matter because it was "a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility." 447 U.S. 303, 310 (1980). The Federal Circuit similarly found in *Natural Alternatives International, Inc. v. Creative Compounds, LLC*, that the claimed combination of natural products was directed to patentable subject matter. 918 F.3d 1338, 1350 (Fed. Cir. 2019). The court explained that the combination of naturally occurring bacteria in *Funk Brothers* was not patent eligible because the combination did not have a different utility from each of the component bacteria individually. *Id.* at 1349. The *Natural Alternatives* court distinguished the patent claim before it, which claimed a combination of two natural products in a dosage form,

from the claim in *Funk Brothers*, because the claimed combination "could have synergistic effects allowing for outcomes that the individual components could not have."[17] *Id*.

In light of the case law, the relevant question is whether the claimed composition of CoQ homologs in claims 5 and 15 has significant utility over—and is thus markedly different from—any combination of CoQ homologs that occurs in nature. That question goes to step one of the *Alice*/*Mayo* framework. *See ChromaDex*, 59 F.4th at 1285; *Natural Alternatives*, 918 F.3d at 1349.

The record shows that the composition recited in claims 5 and 15 has significant utility over what occurs in nature. First, the specification of the '080 patent repeatedly describes the invention as a method of stably retaining reduced CoQ_{10} and preventing its oxidation. *See* PTX 1, col. 1, ll. 24–29 ("[R]educed coenzyme Q_{10} is easily oxidized by molecular oxygen into oxidized coenzyme Q_{10} and therefore, stabilization of reduced coenzyme Q_{10} is an important issue when it is processed into a food, food with nutrient function claims, food for specified health use, nutritional product, nutritional supplement . . . ."); *id*. at col. 2, ll. 26–28 ("The present invention aims at providing a convenient and preferable method and a composition for stably retaining reduced coenzyme Q_{10} by protection against oxidation . . . ."); *id*. at col. 4, ll. 36–45 ("According to the present invention, a stabilization method of reduced coenzyme Q_{10} can be provided by a mere co-presence of an analog of reduced Q_{10} even when multiple components, particularly a reducing agent, are not used as necessary components to protect the reduced coenzyme Q_{10} from oxidation. Therefore, highly safe reduced coenzyme Q_{10} can be provided, which is free of a noxious substance . . . used as a reducing agent."); *id*. at col. 5, ll. 19–26 ("The stabilization method

[17] *Natural Alternatives* was an appeal of a Rule 12(c) grant of judgment on the pleadings. 918 F.3d at 1341. Accordingly, the court did not conclusively determine that the claimed combination had those synergistic effects, but rather held that the pleadings and record at that stage were sufficient to state a claim that the patented combination was "greater than the sum of the parts." *Id.* at 1349.

of the reduced coenzyme Q_{10} of the present invention. . . is a method . . . which suppresses oxidation of reduced coenzyme Q_{10} into oxidized Q_{10} by molecular oxygen, and stably retains the reduced coenzyme Q_{10}.").

Consistent with the specification, Kaneka's corporate representative, Dr. Funahashi, testified that the aim of the '080 patent was to create compositions of ubiquinol that, in specific weight percentages and in combination with reduced CoQ_9 and/or CoQ_{11}, would stabilize the ubiquinol and prevent oxidation. *See* TD1 at 20:1–21:9. Dr. Funahashi explained that "ubiquinol is easily oxidized, and when it oxidizes . . . [it] is not absorbed as easily as the reduced form of CoQ_{10}."[18] *Id*. at 21:2–6. Thus, according to Dr. Funahashi, "if the ubiquinol is not stabilized, then one cannot . . . obtain the expected effects" of taking ubiquinol products. *Id*. at 21:6–9. Dr. Myerson similarly testified that the advantage of the composition in claims 5 and 15 was "stabilizing the reduced coenzyme Q10 against oxidation." *See id.* at 81:9–14.

In support of their patent ineligibility argument, the defendants cite trial testimony that the CoQ homologs exist individually and together in nature. *See* Dkt. No. 231 at 31. The defendants also cite prior art references and documents in the record that show the same. *See id*. But the defendants do not point to any testimony or exhibit establishing that the combinations of CoQ homologs that occur in nature have the same benefit of retaining CoQ_{10} in its reduced form and preventing oxidation. *See id*. at 31–33. That is a marked difference from naturally occurring combinations, with significant utility, as represented in the specification and attested to by Dr. Myerson and Dr. Funahashi.

[18] Thus, contrary to the defendants' assertion, there is trial testimony about increased absorption of reduced CoQ_{10} in the human body, compared to oxidized CoQ_{10}. *See* Dkt. No. 240 at 16 ("The trial testimony cited by Kaneka does not say anything about absorption in the human body.").

The only evidence that the defendants cite to establish that "claims 5 and 15 fail to provide significant utility" is Dr. Myerson's testimony regarding Figures 1 and 2 of the '080 patent. *Id*. at 32–33 (citing TD3 at 58:17–61:21). In their opening brief, the defendants argue that "Dr. Myerson testified that Figures 1 and 2 from the '080 Patent demonstrated no benefit over the individual elements." *Id*. at 32. In their reply brief, the defendants suggest that Dr. Myerson's testimony constitutes "admissions that claims 5 and 15 share no relationship with the rat plasma data contained in the '080 Patent and that claims 5 and 15 conferred no benefit to stability, bioavailability, or absorption." Dkt. No. 240 at 16. I disagree that Dr. Myerson's testimony indicates that claims 5 and 15 fail to provide significant utility.

Dr. Myerson testified that the advantage of the composition recited in claims 5 and 15 is "stabilizing the reduced coenzyme Q10 against oxidation," as stated throughout the specification. *See* TD1 at 81:9–14. And when asked by the defendants' counsel whether improved stability was measured in any way in the '080 patent, Dr. Myerson responded that Table 1 in the '080 patent indicated the results of a stability test. *See* TD3 at 61:22–62:20 ("It's exposing it to air and looking at the results after 24 hours. That's clearly a stability test."); PTX 1, col.14, ll. 36–55. The defendants make no argument about Table 1. Contrary to the defendants' contentions, Dr. Myerson's testimony that Figures 1 and 2 do not match the limitations of claims 5 and 15 has no bearing on his testimony about the advantage of the stability conferred by the '080 patent, particularly given the defendants' lack of any explanation of the significance of Figures 1 and 2.[19]

[19] Figure 1 (a graph showing the total coenzyme Q concentration in rat plasma after administering a reduced CoQ_9 sample versus a reduced CoQ_{10} sample) appears to support the specification's teaching that "since the absorbability of reduced coenzyme Q_9 in the body is greater than that of reduced coenzyme Q_{10}, a composition containing reduced coenzyme Q_9 and reduced coenzyme Q_{10} in combination shows higher absorbability in terms of the total amount of coenzyme Q." PTX 1 at col. 4, ll. 53–58. Figure 2 (a graph showing the total coenzyme Q_{10} concentration

Accordingly, the defendants have not carried their burden of establishing that the composition recited in claims 5 and 15 fails to provide significant utility over what exists in nature. Claims 5 and 15 are not directed to natural phenomena and are thus patent eligible.

B. Anticipation and Obviousness under 35 U.S.C. §§ 102 & 103

"Anticipation requires that a single prior art reference disclose each and every limitation of the claimed invention, either expressly or inherently." *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1306 (Fed. Cir. 2019). Anticipation is a factual question. *See Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1068 (Fed. Cir. 2017).

"Obviousness is a question of law based on underlying findings of fact." *In re Kubin*, 561 F.3d 1351, 1355 (Fed. Cir. 2009). "An analysis of obviousness must be based on several factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness, if any." *Id*. Objective evidence of nonobviousness includes "commercial success enjoyed by devices practicing the patented invention, industry praise for the patented invention, copying by others, and the existence of a long-felt but unsatisfied need for the invention." *Apple Inc. v. Samsung Elecs. Co.,* 839 F.3d 1034, 1052 (Fed. Cir. 2016) (en banc).

"A party seeking to invalidate a patent as obvious must demonstrate by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have

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in rat plasma after administering a reduced CoQ_{10} sample versus a reduced $CoQ_{10} + CoQ_{11}$ sample) appears to support the specification's teaching that when "reduced coenzyme Q_{11} contained in reduced coenzyme Q_{10} [is] ingested, the effect of the reduced coenzyme Q_{10} is not prevented." *Id*. at col. 4, ll. 46–51. Read in this light, Figures 1 and 2 do not support the defendants' position that claims 5 and 15 lack significant utility.

had a reasonable expectation of success from doing so." *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 752 F.3d 967, 973 (Fed. Cir. 2014) (quoting *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009)) (internal quotation marks omitted). Although the patent owner bears the burden of production as to secondary considerations of nonobviousness, the party challenging the patent bears the ultimate burden of proving obviousness. *See Galderma Lab'ys, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013).

1. Anticipation by the '044 Patent

The defendants argue that "claims 5 and 15 are either anticipated or rendered obvious in view of at least the '044 Patent along with the statements contained within the '080 Patent explaining that its compositions are methods are [sic] practiced utilizing nothing more than prior art methods." Dkt. No. 231 at 23. I address first whether the '044 patent anticipates the '080 patent.

The defendants' argument is based on language in the '080 patent acknowledging that the claimed compositions can be prepared by methods known in the prior art, including the method of the '044 patent.[20] *See id*. at 20–21 (citing PTX 1 at col. 1, ll. 6–12; *id*. at col. 5, ll. 48–58). The defendants also cite Dr. Taylor's testimony that "what's being prepared in the '080 Patent is being prepared by the previous art that exists out there in other patents" and that there is, therefore, "nothing new" about claims 5 and 15 of the '080 Patent. *See id*. at 21 (citing TD4 at 11:22–14:8). The defendants further argue that while the '044 patent does not discuss the CoQ_{11} limitation,

[20] The defendants assert that the '080 patent refers to the '044 patent as "WO 03/06408," Dkt. No. 231 at 20 n.12, which Kaneka does not dispute.

Kaneka's infringement case establishes that CoQ_{11} is inherently present with CoQ_{10}.[21] *See id*. at 16; Dkt. No. 240 at 17–18.

Kaneka argues that the defendants have failed to show that each limitation of the asserted claims is disclosed in the '044 patent and that Dr. Taylor admitted at trial that the '044 patent does not disclose each limitation. *See* Dkt. No. 232 at 34. Dr. Taylor testified as follows:

> Q. And, Doctor, the '044 patent does not disclose the limitation of not less than 1.5 weight percent to not more than 99 weight percent of reduced coenzyme Q_9 relative to coenzyme [Q_{10}] . . . right?
> A. It does not.
> Q. And this patent does not discuss Q_{11}, either, right?
> A. No, it does not.

See TD2 at 266:7–14. Kaneka also points to Dr. Myerson's testimony that the '044 patent does not disclose all the claim limitations of the '080 patent. *See* Dkt. No. 232 at 34 (citing TD3 at 34:4–35:17).

Regarding the defendants' inherency argument, Kaneka argues that Dr. Taylor's testimony establishes that CoQ_{11} is not always found in the presence of CoQ_{10}. *See* Dkt. No. 244 at 17–18.

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[21] Citing Dr. Myerson's testimony about the "necessary inclusion of oxidized CoQ_{11} in Defendants' starting material," the defendants argue in their opening brief that "Kaneka cannot have it both ways." Dkt. No. 231 at 16. That is, the defendants contend that "Kaneka cannot prove its infringement theory by relying on the necessary presence of oxidized CoQ_{11} in the oxidized CoQ_{10} that is reduced to make the Accused Products[] while at the same time trying to sidestep invalidating the '080 Patent by asserting that the prior art lacked any express recitation of the necessary presence of oxidized CoQ_{11}." *Id*. As Kaneka points out, however, the defendants mischaracterize Dr. Myerson's testimony. *See* Dkt. No. 244 at 17. Dr. Myerson testified that the presence of reduced CoQ_{11} necessarily entailed the presence of oxidized CoQ_{11} prior to reduction, not that oxidized CoQ_{11} was necessarily found with oxidized CoQ_{10}. *See* TD1 at 97:13–98:4. Contrary to the defendants' assertion, Kaneka's theory of infringement does not rely on the "necessary presence of oxidized CoQ_{11} in the oxidized CoQ_{10}."

It is only in their reply brief that the defendants argue that Kaneka's infringement contentions establish that CoQ_{11} inherently occurs in the presence of CoQ_{10}. *See* Dkt. No. 240 at 14; Dkt. No. 240-1 at 6 ("[I]t is known that a CoQ_{10} composition will include Q_{11}."). I will not consider the defendants' untimely argument about Kaneka's infringement contentions. Even if I did, the testimony at trial does not support a finding that a CoQ_{10} composition inherently includes CoQ_{11}.

Dr. Taylor initially testified that coenzymes "9, 10, and 11 occur together in almost any sample that [he has] looked at," *see* TD2 at 213:3–5, but he later clarified that they do not always occur together, *id*. at 214:24–215:3 ("I said [coenzymes] 9, 10, and 11 can occur together naturally. I didn't say in every absolutely case, if 9 and 10 are together, there will be 11, or if there's 10 and 11 together, there will be 9.").

The record does not support a finding that the '044 patent discloses each limitation of claims 5 and 15 of the '080 patent, either expressly or inherently. As part of Kaneka's infringement case, Dr. Myerson testified that because the defendants' final product contained reduced CoQ_{11}, oxidized CoQ_{11} must have been present prior to the reducing step in the defendants' production. *See* TD1 at 96:15–98:4. That testimony, however, falls short of establishing that CoQ_{11} always occurs with CoQ_{10}. Dr. Taylor's testimony is also insufficient to establish such a broad proposition. It is therefore not inherently the case that CoQ_{10} always occurs with either any amount of CoQ_{11} or the specific amount of CoQ_9 required by claims 5 and 15.[22]

Accordingly, the '044 patent does not anticipate the '080 patent. The '044 patent merely describes a method for reduction that the '080 patent acknowledges would be appropriate to use in creating the claimed composition.

2. Obviousness over the Prior Art

The defendants argue that "[t]he '080 Patent's admissions that its claims can be practiced utilizing nothing more than the disclosure of the '044 Patent and other conventional aspects of the

[22] The defendants suggest that if CoQ_{11} does not inherently occur with CoQ_{10}, then Kaneka has not made its infringement case for claim 15 because there is no other evidence that CoQ_{11} was in the starting composition. *See* Dkt. No. 231 at 16. That is not so. It is entirely consistent with the testimony in this case that (1) oxidized CoQ_{11} was present alongside oxidized CoQ_{10} in the starting composition of the defendants' products and (2) that oxidized CoQ_{11} does not always occur in the presence of oxidized CoQ_{10}.

prior art, coupled with the fact that the '080 Patent identifies no new aspect of producing, isolating, modifying, synthesizing, or otherwise creating the composition of claim 5 under the generic, non-specified prior art step of 'reducing' contained in claim 15 render these claims obvious." Dkt. No. 231 at 23. According to the defendants, the doctrine of claim differentiation dictates that claims 5 and 15 do not have the same purported benefit to stability as claim 1, which expressly refers to a "method for stabilizing reduced coenzyme Q_{10}." *See id*. at 24; PTX 1 at col. 16, ll. 23–36 ("A method for stabilizing reduced coenzyme Q_{10}, which method comprises preparing a reduced coenzyme Q_{10}-containing composition comprising [the composition disclosed in claim 5]."). Apart from the claim differentiation argument, the defendants rely on Dr. Taylor's testimony that he believes "from the Åberg reference, plus the other references that I do mention in . . . my report, plus the '044 patent, it's obvious to me that there's really nothing unique, nothing new about the claims 5 and 15 of the '080 patent." *See* Dkt. No. 231 at 22 (citing TD4 at 21:25–22:10).

The defendants' claim differentiation argument fails. Claim 5 is a composition claim, and claim 15 is directed to a method for producing the composition disclosed in claim 5. Given the subject matter addressed by those claims, there would be no reason for the patentees to refer to stabilization in those claims, unlike claim 1, which claims a method for "stabilizing reduced coenzyme Q_{10}." The absence of an express reference to stabilizing does not establish that the composition and the method disclosed in claims 5 and 15 do not have a stabilizing effect like claim 1—particularly when claims 1, 5, and 15 disclose the same underlying composition.[23] The

[23] The defendants cite Dr. Myerson's testimony as acknowledging that "claims 5 and 15 purported no benefit to stability, bioavailability, or absorption." Dkt. No. 231 at 24. That is, Dr. Myerson acknowledged that claims 5 and 15 lack express references to stability, bioavailability, or absorption, while testifying that "the purpose of the invention of the '080 patent, in general, was . . . stabilizing the reduced form of Q_{10}." *See* TD1 at 163:4–164:25. For the reasons explained above, Dr. Myerson's testimony does not support the defendants' assertion that the composition

specification makes clear that "reduced coenzyme Q_{10} can be stabilized by the co-presence of reduced coenzyme Q_9 and/or reduced coenzyme Q_{11}." PTX 1 at col. 2, ll. 36–41; *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) ("[C]laims must be read in view of the specification, of which they are a part.") (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995)) (internal quotation marks omitted).

As for Dr. Taylor's testimony that claims 5 and 15 are obvious in light of prior art, Kaneka points out that Dr. Taylor's report "failed to propose any ***specific combination of references*** that allegedly rendered the Asserted Claims invalid . . . a fact [he] admitted at trial." Dkt. No. 232 at 35. Kaneka also notes that there is no evidence in the record as to (1) the general knowledge of one skilled in the art at the time of the invention of the '080 patent; (2) the motivation to combine any reference; or (3) any alleged market need, or how a combination could meet an alleged market need. *See id*. at 35–36. In addition, Kaneka argues that there is no evidence that known methods for reducing CoQ10 "would have resulted in the ***specific formulation*** claimed in claims 5 and 15." *See id*. at 36.

Kaneka is correct that Dr. Taylor testified at trial that his report did not include specific combinations of prior art as a basis for asserting obviousness. *See* TD2 at 267:2–268:1 ("Q. Okay. Now, does your report include specific combinations of prior art? A. No, I don't believe we did that."); PTX 82 ¶ 100–102. Moreover, Dr. Myerson testified at trial that there is no prior art reference that discusses "making a composition with the particular properties . . . disclosed in the '080 patent." *See* TD3 at 40:5–19. The defendants do not cite any portion of Dr. Taylor's report or testimony that points to any such composition. Nor do the defendants cite any portion of Dr.

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and the method disclosed in claims 5 and 15 have no stabilizing effect; to the contrary, much of Dr. Myerson's testimony was directed to explaining that the benefit of the claimed compositions was that they stabilized reduced Q_{10}.

Taylor's report or testimony that demonstrates that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention." *See Bristol-Myers Squibb*, 752 F.3d at 973.

Dr. Taylor's report and testimony establish, at most, that the way to arrive at the claimed composition would have been obvious once that claimed composition was discovered, because the method for reduction was known. *See* PTX 82 ¶ 100. There is no evidence, however, as to why one skilled in the art would have been motivated to combine prior art references to achieve the composition claimed in claims 5 and 15. Indeed, Dr. Taylor admitted at trial that his report does not provide "any evidence of alleged design need," nor "evidence of any alleged market pressure." *See* TD2 at 268:10–24. He also acknowledged that his "report does not discuss motivations to make combinations of references" and "provides no evidence of any purported motivations to make any combinations of any prior art." *See id*. at 271:5–13.

"[C]onclusory analysis is insufficient when it bears no relation to any specific combination of prior art elements . . . from specific references and doesn't explain why a skilled artisan would have combined them in the way that the claimed invention does." *Google LLC v. Sonos, Inc.*, No. 2023-1259, 2024 WL 2350509, at *2 (Fed. Cir. May 23, 2024)) (quoting *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 797 (Fed. Cir. 2021)) (cleaned up); *see also Meyer Intell. Props. Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1375 (Fed. Cir. 2012) ("[A]n expert report that merely lists a number of prior art references and concludes that one skilled in the art would find the claims obvious is deficient under Rule 26."); *Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc.*, No. 3:11-cv-345, 2012 WL 6562220, at *20 (E.D. Va. Aug. 13, 2012), *aff'd*, 726 F.3d 1370 (Fed. Cir. 2013) ("[Defendants] cannot merely present a list of prior art combinations and then leave it to the Court

to determine how the references fit together to render the claims obvious."). The defendants therefore have not carried their burden of proof on obviousness.[24]

C. Written Description under 35 U.S.C. § 112

Section 112 requires, in relevant part, that the specification "shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a). "To fulfill the written description requirement, a patent owner must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and demonstrate that by disclosure in the specification of the patent." *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1163 (Fed. Cir. 2019) (quoting *Carnegie Mellon Univ v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008)) (internal quotation marks omitted).

The defendants argue that "[b]ecause no analysis was ever performed to determine the presence of reduced CoQ_{11} in the '080 Patent, and the analytical methods disclosed therein are insufficient to make that determination, there is substantial evidence that the inventors did not possess the full scope of the claims at the time of invention." Dkt. No. 231 at 37. That is, the defendants argue that the '080 patent discloses using HPLC-UV to determine the presence of CoQ_{10} only and that Kaneka's own testing for its infringement case establishes that HPLC-UV is not precise enough to measure small quantities of reduced CoQ_{11}. *See id*. at 36–37. The defendants also argue that all the embodiments involving CoQ_{11} "reference[] CoQ_{11} as if it were inherently

[24] Neither party has focused on any objective considerations that could have a bearing on the obviousness issue in this case.

present as an impurity in the CoQ_{10} material." *See id*. at 35 (citing the portions of the specification that disclose Production Example 4, Preparation Example, and Example 4).

Kaneka responds that claims 5 and 15 are not invalid under section 112, because the specification describes the inventions recited in those claims and the manner and process of making and using them. Dkt. No. 244 at 19–20. As to the "impurity" argument, Kaneka argues that the defendants did not previously raise that argument and that the argument should be rejected for that reason. *Id*. at 19 n.16; *see also id*. at 1. Even if the argument was preserved, however, Kaneka contends that there is no reason to interpret the references to CoQ_{11} in the relevant examples as an "impurity." *See id.* at 19. Regarding the measurements of CoQ_{11}, Kaneka argues that "[d]efendants provide no evidence that measuring for this homolog was not well-known and disclosed in the prior art at the time," and that the asserted claims do not require a specific amount of reduced CoQ_{11}. *Id*.

Both of the defendants' written description arguments fail. In his report, Dr. Taylor did not contend that CoQ_{11} is present in Production Example 4, Preparation Example, and Example 4 only as an impurity. *See* PTX 82 ¶ 109–113 (discussion of section 112). Even if he had made such a contention, it would not have been persuasive, as the specification does not refer to CoQ_{11} as an impurity of CoQ_{10}, and there is no evidence to support that interpretation. *See* PTX 1 at col. 14, ll. 15–16 ("[o]xidized coenzyme Q_{10} (10 g) containing 0.1% of oxidized coenzyme Q_{11}"); *id.* at col. 15, ll. 44–46 ("crystals of reduced coenzyme Q_{10} containing 0.6 wt % of oxidized coenzyme Q_{10} and 0.1 wt % of reduced coenzyme Q_{11}"); *id.* at col. 15, line 67, through col. 16, line 1 ("a mixture of reduced coenzyme Q_{10} and reduced coenzyme Q_{11} (containing 0.1% of reduced coenzyme Q_{11})").

The argument that Kaneka lacked possession of the claimed invention also fails. The defendants rely on the deposition testimony of Dr. Ueda, the inventor of the '080 patent, that reduced CoQ_{11} was never measured "because there was not a need to do so." *See* Dkt. No. 231 at 36 (citing TD2 at 46:2–8). That testimony is consistent with Dr. Myerson's testimony that a CoQ homolog that is present in some amount in the starting composition in an oxidized state (as claim 15 requires) will be present in a reduced state after reduction. *See* TD1 at 96:20–98:4. The defendants have presented no evidence to the contrary. Moreover, because claims 5 and 15 require only that reduced CoQ_{11} be present in the final product, not that it be present in a specific proportion, there is no need for a precise measurement of the amount of reduced CoQ_{11} that is found in the final product. Finally, even if there were such a requirement, the defendants have not shown that methods for measuring CoQ_{11} in small quantities, such as by the LC-MS/MS testing that Dr. Myerson used, were unknown to persons of skill in the art.

Accordingly, the defendants have failed to establish invalidity under section 112.

CONCLUSION

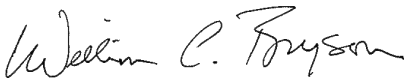
Based on the foregoing findings and legal analysis, I conclude as follows:

1. Kaneka has proved, by a preponderance of the evidence, that the accused products infringe claims 5 and 15 of the '080 patent;
2. Kaneka has failed to prove, by a preponderance of the evidence, that ARN induced infringement of the '080 patent by DFH;
3. Kaneka has failed to prove, by a preponderance of the evidence, that the defendants' infringement of the '080 patent was willful;
4. The defendants have failed to prove, by clear and convincing evidence, that the asserted claims of the '080 patent are invalid.

Having determined the defendants are liable for infringing Kaneka's valid patent claims, the court will hold a separate trial on damages, as provided in the court's May 16, 2024, order bifurcating the liability and damages phases of the case. Dkt. No. 203. The arrangements for scheduling further proceedings, including the damages trial, if necessary, will be addressed in a separate order.

IT IS SO ORDERED.

SIGNED this 20th day of December, 2024.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE